

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/588,574

Applicant(s)

BENCHMARK, STIG

Examiner

KADE ARIANI

Art Unit

1651

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 December 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Attachment.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 12-26.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
The claims remain rejected for the reasons of record.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Ruth A. Davis/
Primary Examiner, Art Unit 1651

Applicant's reply have overcome the rejection of Claims 12-23 under 35 U.S.C. 112, first paragraph.

Applicant argues that while Kruszewskya discloses each of the noted strains, it does not teach or suggest a formulation comprising all four of strains as recited in pending claims.

However, Kruszewskya teaches the selected LAB strains have shown to survive and multiply during the acid and bile stress conditions of human stomach and upper intestine and they have a prominent ability to colonise the human large intestine, (p.43 2nd column last paragraph and p.44 1st column 1st paragraph). Kruszewskya teaches LAB have a GRAS (generally regarded as safe) status, and have been widely used in food industry and there is an increasing interest to add selected strains to food items to treat various diseases, such as infections, allergy, inflammatory bowel disease, and cancer (p.43 1st column 1st paragraph).

Moreover, Kaur et al. teach a probiotic preparation comprising multiple strains of probiotic strains for treating ulcerative colitis (an stress-induced inflammation) (p.4 Table 1., VSL#3). Kaur et al. further teach synbiotics (a mixture of probiotics and prebiotics) overcome the limitations of probiotics and improve the survival and implantation of live microbial dietary supplement (p.7 2nd column 2nd paragraph). Therefore, a person of ordinary skill in the art at the time the invention was made could have been motivated to administer a combination of the four strains as taught by Kruszewskya and the results would have been predictable. As indicated in MPEP "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

Applicant argues that a person of ordinary skill in the art would have not been motivated to include *Leuconostoc mesenteroides* 23-77:1, because there is no data in Kruszewskya supporting the production of anti-inflammatory cytokines.

However, as mentioned immediately above, Kruszewskya teaches the tested strains ferment fibers and they should exert a beneficial effect on the colonic flora and possibly act as a prebiotic since they ferment inulin, a nondigestible fructan, which has been shown to stimulate the growth of *Bifidobacteria* (p.44 2nd column 2nd paragraph). Thus, a person of ordinary skill in the art at the time the invention was made could have been motivated to use the strains for their ability to ferment fibers and as a prebiotic.

Applicant argues that the production of pro-inflammatory cytokine IL-8 by *Lactobacillus paracasei* subsp *paracasei* F-19 as taught by Kruszewskya, would discourage a person of ordinary skill in the art to even consider including *Lactobacillus paracasei* subsp *paracasei* F-19 in a formulation to be used to treat stress-induced inflammatory disorder.

However, Kruszewskya teaches a mild immunostimulatory effect was exerted by *Lactobacillus paracasei* subsp *paracasei* F-19 (p.45 1st column 2nd paragraph lines 1-4), it must also be noted that IL-8 is a mediator of the immune reaction in the innate immune system response which provide immediate defense against infection and is not long lasting. Moreover, Kaur et al. teach it is a well-established fact that by probiotic therapy resistant to pathogen and immune stimulation (non-specific immune response) can be achieved (p.7 1st column last paragraph, and p.5 2nd column 2nd paragraph). Thus, a person of ordinary skill in the art at the time the invention was made could have motivated to use the immune stimulation exerted by *Lactobacillus paracasei* subsp *paracasei* F-19 in order to provide resistant to pathogens.